

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

Page 1 of 78 pages

1. Purchase Authority: Public Law 92-218 as amended

2. Request For Proposal (RFP) Number: RFP N02-PC-65008-58	3. Issue Date: March 21, 2006	4. Just In Time [] NO [X] YES See Part IV Section L	5. Set Aside: [X] NO [] YES See Part IV Section L
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6. TITLE: Development and Technical Services for the NCI Applied Research Program

7. ISSUED BY: Virginia A. DeSeau Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6002 6120 EXECUTIVE BLVD MSC 7195 BETHESDA MD 20892-7195	8. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
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9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place and in the number of copies specified in Attachment 1 until **4:00 PM local time (EST) on May 1, 2006**. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."

10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF FAR CLAUSE 52.215-1, ENTITLED, "INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION" LOCATED IN SECTION L.1. OF THIS SOLICITATION.

11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract.
(<http://www.ccr.gov>)

12. FOR INFORMATION CALL: Virginia A. DeSeau
PHONE: (301-435-3798; E-mail: vd9t@nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

Virginia A. DeSeau
Contracting Officer
Office of Acquisitions
National Cancer Institute

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PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This procurement will provide services to assist the Applied Research Program (ARP), in the Division of Cancer Control and Population Sciences, within the National Cancer Institute (NCI) in developmental and technical services related to existing data, studies or research. Such assistance will involve: development of new instruments (particularly dietary instruments or programs), including cognitive testing; maintaining or modifying questionnaire or other research databases; translations of materials into multiple languages; programming and management related to previous studies or new questionnaires; literature reviews, as necessary; management, tracking, transport or analyses of existing biological specimens; assistance in development of materials for clearance by the Office of Management and Budget (OMB) or NCI Institutional Review Boards (IRBs); and in writing various types of reports.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated 1/26/2006, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods.

1. **Monthly:** The Contractor will provide technical monthly progress reports. These reports will include progress on all projects in the past month, whether or not each project is on schedule, whether any problems were encountered in the collection, handling, processing of any data or biological specimens, including resolution of the problems. An electronic copy and one hard copy of reports will be delivered to the Project Officer within 15 calendar days of the end of the reporting period. The monthly progress report is not required on the month that the annual progress report is due.
2. **Annual Progress Reports:** The Contractor will provide annual technical progress reports. This report will include a summary of all projects in the past year, including a summary of whether or not each project is on schedule, whether any problems were encountered in the collection, handling, processing of any data or biological specimens, including resolution of the problems. An electronic copy and one hard copy of reports will be delivered to the Project Officer within 15 calendar days of the end of the year from the date that the contract was awarded.
3. **Final Report:** The Contractor will provide a final technical report that summarizes the work completed for each project and includes a detailed listing of each deliverable, its contents, when it was delivered, and to whom it was delivered. The final report will also include, as appropriate, any source code and/or databases (original or revised).

b. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

c. Other Reports/Deliverables

1. **As assigned, with due dates integrated:** For each specific project, NCI will provide a detailed project request. The Contractor will have one week to respond with questions, a schedule for deliverables, and a task-specific budget. A final plan with deliverables and a budget for the

specific project will be finalized and agreed upon one week later. No work is to proceed before finalizing the time line, budget, and deliverables for each specific project requested of the Contractor.

2. Deliverables within the projects will be specified and will include, but not be limited to: project protocols, data files, databases, reports, literature reviews, questionnaires (paper and/or electronic), data analysis report papers, training and procedure manuals, OMB packages, IRB packages, software, codebooks, and scanning programs. Upon completion of each project, source codes/object codes will be delivered along with all data files for the particular project.

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. PACKAGING

All deliverable required under this contract will be packaged, marked, and shipped in accordance with Government specifications. The Contractor will guarantee that all materials will be delivered in immediate usable and acceptable condition.

ARTICLE D.2. MARKING

The contract number will be placed on or adjacent to all exterior mailing or shipping labels of deliverable items called for by the contract.

ARTICLE D.3. SHIPPING

All shipping and handling will be in accordance with the Center for Disease Control (CDC) standards contained in 42 CFR Ch.1 Part 72 (10/1/88), which sets forth the requirements covering the shipment of etiologic agents, if any. 42 CFR Ch.1 Part 72 (10/1/88) is hereby incorporated by reference.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed by the Project Officer at the address listed in the clause, "Project Officer" in Section G of the contract. .

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract is anticipated to be from September 30, 2006 through September 29, 2011.
- b. If the Government exercises its option(s), the period of performance will be increased as listed below:

Option Number	Option Period
Option #1	9/30/2011 - 9/29/2012
Option #2	9/30/2012 - 9/29/2013

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract:

Item	Description	Quantity	Delivery Schedule
(a)	Monthly Progress Reports	2	To be determined at award
(b)	Annual Progress Reports	2	To be determined at award
(c)	Project Specific Deliverables, e.g., data files, questionnaires, report papers, software, manuals, codebooks, data analyses	2	To be determined during contract
(d)	Final Report	2	To be determined at award
(e)	Summary of Salient Results	2	To be determined at award

- b. The above items shall be addressed and delivered to:

[The specific information will be included in the resultant contract]

Addressee	Deliverable Item No.	Quantity
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ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

The personnel specified in this contract are considered to be essential for the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor will notify the Contracting Officer reasonably in advance and will submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion will be made by the Contractor without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing such diversion and such ratification will constitute the consent of the Contracting Officer required by this clause. The contract may be amended during the course of the contract to either add or delete personnel, as appropriate.

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME

TITLE

[To be specified prior to award]]

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT: NIH (RC)-4

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

- (a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, e.g. HHSN261200611000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, e.g. N02-PC-61100.)

- (b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions
National Cancer Institute, NIH
EPS, Room 6002
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 435-3798.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion

of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, entitled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/cbt.html>. This site may be downloaded at no cost and modified for use by the offeror, if desired. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirements.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor will provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.2. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.3. NEEDLE EXCHANGE

- a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. Public Law and Section No.	Fiscal Year	Period Covered
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[Applicable information to be included at award]

ARTICLE H.4. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as a referenced Attachment in Section J.

ARTICLE H.5. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of five years for the conduct of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-9 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform two additional years of the Statement of Work as also defined in Sections C and F of this contract. If the Government exercises these options, notice must be given at least 60 days before the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in Section B.

ARTICLE H.6. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

- (1) The Small Business Subcontracting Plan will be provided prior to contract award and will be attached hereto and made a part of the resultant contract in Section J.
- (2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS)" at <http://www.esrs.gov>.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/or title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

[to be inserted at time of award]
[Contracting Officer, OA, NCI]

ARTICLE H.7. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to develop or access Federal automated information systems; therefore, the Contractor shall comply with the "DHHS Information Security Program Policy" (<http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc>) as set forth below. The Contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

**** (NOTE: The resultant contract will include the Information Type, however for the purposes of this RFP, the Information Type is specified in SECTION L.2.b.9 Technical Proposal Instructions of this RFP.) ****

[X] Administrative, Management and Support Information:

[X] Mission Based Information:

b. Security Categories and Levels

**** (NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b.9 Technical Proposal Instructions of this RFP.) ****

Confidentiality	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Overall	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

c. Position Sensitivity Designations

- (1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

**** *(NOTE: The resultant contract will include the Position Sensitivity Designations, however for the purposes of this RFP, the Position Sensitivity Designations applicable to this RFP are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)* ****

- [] **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).
 - [] **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
 - [] **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).
- (2) The Contractor shall submit a roster, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at:
<http://ais.nci.nih.gov/forms/Suitability-roster.xls>
- Upon receipt of the Government's notification of applicable Suitability Investigation required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.
- Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.
- (3) Contractor employees shall comply with the DHHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c.(2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor employee to work under the contract.

d. Systems Security Plan

The Contractor shall protect Federal automated information systems that are developed or accessed

by the Contractor. System security shall be accomplished in accordance with the Contractor's System Security Plan dated _____. The plan must::

- (1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The Contractor shall use the **NIH Systems Security Plan Template** (detailed) at <http://irm.cit.nih.gov/security/secplantemp.doc> or **NIH Systems Security Plan Outline** (outline only) at http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

[OR (To be determined during negotiations)]

- (1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to, administrative, technical, and physical security as follows:
 - (i) Security Awareness Training
 - (ii) Logical Access Control
 - Network (ex: firewall)
 - System (ex: network OS, tcp wrappers, SSH)
 - Application (ex: S-LDAP, SSL)
 - Remote Access (ex: VPN)
 - Monitoring and support (ex: IDS, pager, NOC)
 - (iii) Protection against data loss
 - OS security (ex: patch management, configuration)
 - Application security (ex: patch management)
 - Database security
 - Back-up and recovery
 - Fault tolerance, high availability
 - (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
 - (v) Physical Security
 - Access control (ex: locks, guards)
 - Power conditioning and/or UPS
 - Air conditioning
 - Fire protection

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

The Contractor shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (<http://irtsectraining.nih.gov/>) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The Contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor

staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:

**** *[Additional courses will be listed here in the resultant contract, if applicable.]* ****

g. Personnel Security Responsibilities

The Contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive Department information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each contractor employee who may have access to sensitive Department information under this contract shall complete Commitment To Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

i. References

1. DHHS Information Security Program Policy: <http://www.hhs.gov/ohr/manual/pssh.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIST Special Publication 800-16, Information Technology Security Training Requirements: <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>
Appendix A-D: <http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf>
4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: <http://csrc.nist.gov/publications/nistpubs/index.html>
5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf>
6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf>
7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: <http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf>
8. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>
9. Roster of Employees Requiring Suitability Investigations: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>
10. NCI Information Technology Security Policies, Background Investigation Process:

- <http://ais.nci.nih.gov/>
11. NIH Systems Security Plan Template (detailed): <http://irm.cit.nih.gov/security/secplantemp.doc>
 12. NIH Systems Security Plan Outline (outline only): http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
 13. NIH Information Technology General Rules of Behavior: <http://irm.cit.nih.gov/security/nihitrob.html>
 14. Commitment To Protect Non-Public Information - Contractor Agreement: <http://irm.cit.nih.gov/security/Nondisclosure.pdf>

ARTICLE H.8. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at <http://www.access-board.gov/>.

The standards applicable to this requirement include software applications and operating systems, web-based intranet and internet information and applications, telecommunications products, and video and multimedia products.

ARTICLE H.9. PUBLICATION AND PUBLICITY (ACKNOWLEDGMENT LANGUAGE)

The Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No.

ARTICLE H.10. PUBLICATIONS AND PUBLICITY (DISCLAIMER LANGUAGE)

- (a) Unless otherwise specified in this contract, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication will be promptly sent to the Project Officer. The Contractor will also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.
- (b) The Contractor will include in any publication resulting from work performed under this contract a disclaimer reading as follows:

"The content of the publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products or organizations imply endorsement by the U.S. Government."

ARTICLE H.11. PRESS RELEASES

- a. Pursuant to Public Law(s) cited in paragraph b., below, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

b. **Public Law and Section
No.**

Fiscal Year

Period Covered

[Applicable information to be included at award]

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.13. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. **Service Involving the Use of Information Technology**

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

2. **Noncommercial Supply Items Warranty**

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The Contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the Contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item

whose noncompliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The Contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product documentation provided by the Contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the Contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

ARTICLE H.14. ANTI -LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. No.	Public Law and Section	Fiscal Year	Period Covered
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[Applicable information to be included at award]

ARTICLE H.15. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : <http://ott.od.nih.gov/NewPages/64FR72090.pdf>, is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://www.usfa.fema.gov/hotel/index.htm>

ARTICLE H.17. PLAIN LANGUAGE

The NIH supports the June 1, 1998 Presidential Memorandum on Plain Language and accordingly encourages clear communication. The Contractor will prepare all reports that are required by this contract with the need to communicate clearly in mind. The key to plain writing is identifying the audience. The Contractor should recognize its audience and write accordingly. Information about the plain language initiative can be accessed at: <http://www.plainlanguage.gov> .

ARTICLE H.18. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

ARTICLE H.19. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):

- Questionnaires related to possible pilot studies

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Service Contract (could include Cost Plus Fixed Fee)

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp>

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which **will be based on the type of contract/Contractor will be determined during negotiations.**

It is expected that the following clause(s) may be made part of the resultant contract:

Alternate II (April 1998) of FAR Clause **52.215-2, Audit and Records--Negotiation** (June 1999) is added.

Alternate I (April 1984), of FAR Clause **52.227-1, Authorization And Consent** (July 1995) is deleted in its entirety.

Alternate I (July 1985), of FAR Clause **52.245-5, Government Property (Cost-Reimbursement, Time-And-Material, Or Labor-Hour Contract)** (January 1986) is deleted in its entirety.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (March 1997) is substituted therefor.

FAR Clause **52.232-17, Interest** (June 1996) is added.

Alternate I (July 1985) of FAR Clause **52.245-5, Government Property (Cost-Reimbursement, Time-And-Material, Or Labor-Hour Contracts)** (January 1986) is deleted.

FAR Clause **52.249-5, Termination For Convenience Of the Government (Educational And Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.

HHSAR Clause **352.249-14, Excusable Delays** (April 1984) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed two years."

(2) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[] Offeror elects to waive the evaluation preference."

(3) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

(4) FAR Clause **52.224-2, Privacy Act** (April 1984).

(5) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(6) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Specific data items that are not subject to paragraph (j) include: none

(7) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(8) FAR Clause **52.227-17, Rights in Data--Special Works** (June 1987).

(9) FAR Clause **52.227-19, Commercial Computer Software--Restricted Rights** (June 1987).

(10) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(11) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).

(12) FAR Clause **52.237-3, Continuity of Services** (January 1991).

(13) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(14) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003)

(15) FAR Clause **52.251-1, Government Supply Sources** (April 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

- (1) HHSAR Clause **352.224-70, Confidentiality of Information** (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).
- (2) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).
- (3) HHSAR Clause **352.270-8, Protection of Human Subjects** (March 2005).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

- (1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

- a. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2006)
 - (a) The Contractor shall comply with agency personal identity verification procedures identified in the contract that implement Homeland Security Presidential Directive-12 (HSPD-12), Office of Management and Budget (OMB) guidance M-05-24, and Federal Information Processing Standards Publication (FIPS PUB) Number 201.
 - (b) The Contractor shall insert this clause in all subcontracts when the subcontractor is required to have physical access to a federally-controlled facility or access to a Federal Information system.
- b. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)
 - (a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.
 - (b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who

are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.nlrb.gov>.

- (c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.
- (d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.
- (e) The requirement to post the employee notice in paragraph (b) does not apply to--
 - (1) Contractors and subcontractors that employ fewer than 15 persons;
 - (2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;
 - (3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;
 - (4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--
 - (i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
 - (ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or
 - (5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.
- (f) The Department of Labor publishes the official employee notice in two variations; one for contractors

covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

- (1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;
 - (2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or
 - (3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.
- (g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 4:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 5:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 6:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 7:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310)	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 8:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 9:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 11:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/sps/spshecl.xls
Attachment 12:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 14:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 15:	Privacy Act System of Records <i>System of Records No. 09-25-0200 is applicable to this RFP.</i>	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 16:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 17:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 18:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 19:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 20:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions.* As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be

considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
 - (3) It is the only proposal received.
 - (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
 - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
 - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
 - (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
 - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
 - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
 - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).
 - (e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any

data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

- (2) The Government may reject any or all proposals if such action is in the Government's interest.

- (3) The Government may waive informalities and minor irregularities in proposals received.

- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted,

the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
 - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
 - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iv) A summary of the rationale for award.
 - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
 - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

- (f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **"JUST IN TIME" PROVISIONS**

This RFP contains special procedures for the submission of business management proposals. These special

procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, and the subcontracting plan will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit **an acceptable** subcontracting plan.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541990 [and the Standard Industrial Classification (SIC) code for this acquisition is 8733] .
- (2) The small business size standard is \$6.5 million (average annual receipts for three preceding fiscal years).

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2006.

It is anticipated that the award from this solicitation will be a multiple-year Cost Reimbursement, Completion type contract with a period of performance of five years plus two Option years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 1.3 person years per year and approximately 9 person years over all seven years, if the Options are exercised (1 full-time equivalent or 100% effort = 1 person year). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors will direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration will be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government or to not make any award at all, cost and other factors considered.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Virginia A. DeSeau, Contracting Officer
Office of Acquisitions
National Cancer Institute
EPS, Room 6002
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

- (b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information above) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL (attachment link in Section J of this RFP). Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment link entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Section J, Attachment link entitled, TECHNICAL PROPOSAL COST SUMMARY).

However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Privacy Act - Treatment of Proposal Information**

[Note - the Privacy Act differs from the privacy Rule; The Privacy Rule is defined by the Health Insurance Portability and Accountability Act of 1996 (HIPPO)]

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(9) Selection of Offerors

- a) The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FAR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

(10) Past Performance Information

- a) Offerors shall submit the following information as part of their technical proposal.

A list of the last five contracts completed during the past three years and all contracts awarded currently in process that are similar in nature to the workscope of this solicitation. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as a subcontract that exceeds \$25,000.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(11) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

- a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and
- b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at <http://www.section508.gov> .

(12) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
- b) Facilities Capital Cost of Money, FAR Clause 52.215-16 (October 1997)
- c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8 (October 1997)

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

b) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) **Resumes**

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (See Section M, hereof).

(3) **Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.
- c) See Section J, Attachment by link, entitled, "ADDITIONAL TECHNICAL INSTRUCTIONS."

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following paragraphs (5) through (7) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

[Note - since this contract is not for clinical research, does not require the Contractor to define specific study populations, and will include human subjects only as defined by the Government or through support of existing research projects, the offeror(s) will not be required to submit plans with their proposal for the inclusion of women, minorities or children. During contract performance, it is anticipated that the Contractor will not be required to deliver inclusion reports specific to the aforementioned populations; but the inclusion of women, minorities and children should be taken into consideration in the development and conduct of potential pilot studies. The offeror, and any subcontractor(s), IS required to be in compliance with all other requirements for the handling of human subjects or human subject materials.]

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

- (a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.
- (b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.
- (c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- (d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.
- (e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at <http://www.hhs.gov/ohrp/> or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html
- (f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(6) Instructions to Offerors Regarding Protection of Human Subjects

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

- (a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the [NIH Guide for Grants and Contracts Announcement](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/>. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at

http://www.centerwatch.com/order/pubs_profs_protect.html.

In addition, the NCI sponsors an online training course at:

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

(9) **Information Technology Systems Security**

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "Information Security."

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc>), the following requirements apply:

(a) Information Type

☒ [X] Administrative, Management and Support Information:

☒ [X] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	<input checked="" type="checkbox"/> [X] Low	<input type="checkbox"/> [] Moderate	<input type="checkbox"/> [] High
Integrity	Level:	<input type="checkbox"/> [] Low	<input checked="" type="checkbox"/> [X] Moderate	<input type="checkbox"/> [] High
Availability	Level:	<input checked="" type="checkbox"/> [X] Low	<input type="checkbox"/> [] Moderate	<input type="checkbox"/> [] High

Overall	Level:	<input type="checkbox"/> [] Low	<input checked="" type="checkbox"/> [X] Moderate	<input type="checkbox"/> [] High
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(c) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

☐ [] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[X] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI). [For example, a database administrator or applications programmer]

[X] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI). [For example, a help desk employee or a quality control programmer]

Upon award, the Contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(d) Systems Security Plan

The offeror's proposal must:

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

- (i) Security Awareness Training
- (ii) Logical Access Control
 - Network (ex: firewall)
 - System (ex: network OS, tcp wrappers, SSH)
 - Application (ex: S-LDAP, SSL)
 - Remote Access (ex: VPN)
 - Monitoring and support (ex: IDS, pager, NOC)
- (iii) Protection against data loss
 - OS security (ex: patch management, configuration)
 - Application security (ex: patch management)
 - Database security
 - Back-up and recovery
 - Fault tolerance, high availability
- (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
- (v) Physical Security
 - Access control (ex: locks, guards)
 - Power conditioning and/or UPS
 - Air conditioning
 - Fire protection

Include an acknowledgment of its understanding of the security requirements.
Provide similar information for any proposed subcontractor developing or accessing an AIS.

The SSP that the offeror must submit with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

(e) Information Systems Security Training

DHHS policy requires contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course(<http://irtsectraining.nih.gov/>) prior to

performing any contract work, and on an annual basis thereafter, during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (<http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Cost and Pricing Data

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (6) Proposed cost; profit or fee; and total;
- (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (10) Date of submission; and
- (11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- (2) The nature and amount of any contingencies included in the proposed price.

- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
 - (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For inter-organizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the Contractor, explain the pricing method (see FAR 31.205-26(e)).
 - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime Contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime Contractor's Certificate of Current Cost or Pricing Data. The prime Contractor is responsible for updating a prospective subcontractor's data. For

standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For inter-organizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
 - (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers.
 - (4) Patent application serial numbers, or other basis on which the royalty is payable.
 - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - (6) Percentage or dollar rate of royalty per unit.
 - (7) Unit price of contract item.
 - (8) Number of units.
 - (9) Total dollar amount of royalties.
 - (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).
- F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

- 4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

[NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) will be submitted with the initial proposal. Other documentation to justify costs that will not be required with the initial proposal are included in the 'Just in Time' Provisions (see Section L.1.b above)]

(3) Small Business Subcontracting Plan

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.b. of this RFP.

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
 - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 - (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZONE Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 - (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 - (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 - (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

- (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
- (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZONE, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZONE, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.
 - (4) A description of the method used to develop the subcontracting goals.
 - (5) A description of the method used to identify potential sources for solicitation purposes.
 - (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZONE, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
 - (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZONE, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
 - (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
 - (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
 - (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZONE, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

15% for Small Business; _5_% for Small Disadvantaged Business; _2_% for Women-Owned Small Business; _1_% for HUBZONE Small Business; and _1_% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(4) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HubZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZONE firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

(5) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes* is: <http://www.arnet.gov/References/sdbadjustments.htm>.

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	10%	\$100,000
SDB Participation by subcontractors	15%	\$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(6) **Total Compensation Plan - Instructions**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.b. of this RFP.]

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by re-competition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors included in the competitive range will be required to submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(7) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor

Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(8) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(9) **Other Administrative Data**

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
 - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38, (May 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(10) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.
- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

(11) **Proposer's Annual Financial Report**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.b of this RFP.]

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(12) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(13) Travel Costs/Travel Policy

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.b. of this RFP.]

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are approximately equal to cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. HUMAN SUBJECT EVALUATION [To be evaluated by the Technical Evaluation Panel (TEP)]

This project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FAR). Once discussions are closed with the submission of your FAR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(b) Women and Minorities [As noted on page 46 of this RFP, it is understood that study populations will be defined by the Government, but the offeror should consider the following issues for potential pilot studies]

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if

applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
 - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
 - inclusion of those groups would be inappropriate with respect to their health,;or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FAR). Once discussions are closed with the submission of your FAR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

- (c) **Children** [As noted on page 46 of this RFP, it is understood that study populations will be defined by the Government, but the offeror should consider the following issues for potential pilot studies]

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FAR). Once discussions are closed with the submission of your FAR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FAR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. **EVALUATION OF OPTIONS**

It is anticipated that any contract awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options. (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement,

except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. **TECHNICAL EVALUATION CRITERIA** **TOTAL POINTS: 100**

The evaluation criteria are used by the Technical Evaluation Panel when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

I. Method/Approach

45 Points

The offeror will fully describe the responsibilities of each member of the team proposed and how this team can meet project needs. Approaches to how methods and procedures are developed for the projects should be clearly described and should include methods by which project schedules are developed and tracked. The technical approach should also include a discussion of how problems and quality control concerns will be handled and solved. The technical proposal should describe, in detail, justify, and document procedures used to:

1. Develop and design questionnaires, especially dietary questionnaires
2. Develop systems for overseeing projects or studies
3. Create data files or programs for projects or studies
4. Design and conduct cognitive testing of surveys or questionnaires
5. Translate questionnaires or interviews into multiple languages
6. Link databases
7. Conduct literature searches
8. Manage aspects of biological specimen transport and analysis
9. Prepare, pre-test and evaluate study materials
10. Train abstractors, interviewers, coders, others involved in conducting pilot studies
11. Perform clerical duties, as needed
12. Develop tracing management systems
13. Develop quality control procedures
14. Design and maintain computer databases and reporting software

II. Total Personnel

40 Points

The offeror will provide the necessary support staff to carry out all aspects of the Statement of Work. The offeror will fully describe the responsibilities of each member of the team proposed and how this team can meet project needs. The offeror will document the relevant experience of any persons proposed and will justify the need for persons with various capabilities. *Curriculum vitae* are required for key personnel. Bio-sketches are required for all other personnel. Examples of expected expertise include a project manager, programmer/analysts, nutritionist, cognitive psychologist, expertise in dietary assessment methods, technical support personnel, and administrative/clerical support.

III. Corporate Experience and Resources

15 Points

Offerors should document their corporate, as opposed to individual, personnel experience and resources relevant to the work identified in the Statement of Work of this RFP. This should include corporate experience in:

- (a) Conducting nutrition research, specifically with studies that involve the use of dietary assessment instruments, including Food Frequency Questionnaires (FFQs), food records or 24-hour dietary recalls using differing modes of administration
- (b) Analyses of dietary data, including those from national surveys
- (c) Familiarity of the Automated Multiple Pass Methodology (AMPM) system
- (d) Designing and maintaining computer databases
- (e) Developing and carrying out rounds of cognitive testing of new questionnaires using differing modes of administration
- (f) Developing research plans, scheduling, and writing reports based on work conducted
- (g) Translating interviews or questionnaires into multiple languages
- (h) Managing and manipulating large data sets

- (i) Managing, shipping, tracking, quality control, and storage of biological specimens
- (j) Developing tracking and management systems for studies

Offerors should describe available resources and facilities necessary to complete the project.

5. **PAST PERFORMANCE FACTOR** [To be evaluated by the Government]

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The following rating method shall be used in the evaluation of past performance information:

- +2 **Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.
- +1 **Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.
- 0 **None** - No past performance history identifiable.
- 1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.
- 2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

6. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION** [To be evaluated by the Government]

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantage Business Participation targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J -
List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

Attachment 1

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING

In addition to the address cited below, mark each package as follows:

"RFP NO. N02-PC-65008-58

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

NUMBER OF COPIES

TECHNICAL PROPOSAL: **ORIGINAL* AND 9 COPIES TO:**

BUSINESS PROPOSAL: **ORIGINAL* AND 4 COPIES TO:**

If hand-delivered or delivery service

Virginia A. DeSeau
Contracting Officer
Office of Acquisitions
National Cancer Institute
Executive Plaza South, Room 6002
6120 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Virginia A. DeSeau
Contracting Officer
Office of Acquisitions
National Cancer Institute
Executive Plaza South, Room 6002
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Any package sent to the Rockville address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."

STATEMENT OF WORK

(January 26, 2006)

Attachment 3

Background:

The Risk Factor Monitoring and Methods Branch (RFMMB) within ARP is responsible for surveillance of and monitoring cancer-related risk factors among the general US population and among selected population subgroups defined by gender, age, race and ethnicity; developing and improving the methods of assessing such risk factors; and providing data to assist in formulating public policies addressing these factors. Research in ARP focuses on such factors as food and nutrient intakes, nutritional biomarkers, tobacco use, weight status, energy balance, physical activity, sun exposure, and genetic susceptibility.

In addition, the RFMMB works toward improvements in exposure assessment methods that are utilized in cancer risk factor surveillance activities and facilitates measurement of risk factors for epidemiological research within NCI and among the extramural community. Similar to surveillance research, methods research is conducted using large survey samples designed to be nationally representative. Research in this area includes assessment of diet and closely related factors that are directly associated with cancer risk and also may confound diet and cancer associations, e.g., physical activity, weight history, and genetic susceptibility. Most diet-related assessment research has focused on improvements in self-reporting and validation/calibration of food frequency questionnaires, development of targeted dietary instruments for use in community settings, and development of methods to characterize lifetime weight patterns. Tobacco assessment research supported by NCI for the evaluation of tobacco control includes the development of measures of tobacco use among at-risk populations, household, workplace, economic, and legislative policies, and media advocacy that influence tobacco use, and the evaluation of the effect of the American Stop Smoking Intervention Study (ASSIST) on tobacco use. These questionnaire activities have frequently utilized extensive cognitive testing and pilot work during the early phases of development. Numerous methodological resources have been or are in the process of being developed or analyzed by NCI to assess diet and related risk factors, including a new food frequency questionnaire and related software and brief instruments, or screeners, for assessing fruit and vegetable intake and fat intake.

For the past five years, the RFMMB has used task order contracts to assist in a number of ongoing activities and studies requiring technical support on an ad hoc basis. The first four years, the contract was awarded and administered through the Department of Health and Human Services, Program Support Center (DHHS PSC). Westat (in Rockville, MD) received that contract. This past year (FY 05), a task order for this support was again awarded to Westat through the NCI competitive Task Order contracting mechanism.

SCOPE

This procurement is designed to assist the Applied Research Program (ARP), in the Division of Cancer Control and Population Sciences (DCCPS), within the National Cancer Institute (NCI) in the developmental and technical services related to data, studies or research that evaluate patterns and trends in cancer-associated health behaviors, practices, genetic susceptibilities, health services and outcomes.

Task 1: Maintain and update a nutrient database for a Food Frequency Questionnaire (FFQ) of the NCI Diet History Questionnaire, an automated self administered 24-hour recall, or other dietary questionnaires

Subtask 1.1

The Contractor will use the most current Nutrition Data Systems for Research (NDS-R), developed at the University of Minnesota, to link food codes to national dietary data [such as USDA's Continuing Food Intake by Individuals or the National Health and Nutrition Examination Survey (NHANES), which uses USDA's Food and Nutrient Data for Dietary Surveys (FNDDS)] for purposes of adding and updating nutrients to the NCI FFQ, the Diet History Questionnaire (DHQ). This requires revisions as NDS-R is updated and maintenance of a licensing agreement with the University of Minnesota for use of NDS-R to create databases for FFQs or other automated self-administered 24-hour recall questionnaires.

Subtask 1.2

The Contractor will use other data sources provided by the Government to add other dietary constituents to the nutrient database for dietary assessment instruments. This may or may not require linking to national dietary data as described in subtask 1.1 above.

Subtask 1.3

The Contractor will conduct literature searches, as directed by the Project Officer, to update and maintain the nutrient database for the DHQ.

Subtask 1.4

In conducting this activity, the Contractor will design and maintain computer databases and associated reporting software, edit programs and correct files when necessary, update files with follow-up data, report errors. Such software may include, but not be limited to SAS, Microsoft Excel or Microsoft Access.

Task 2.0: Develop new or modify existing dietary questionnaires

Subtask 2.1

The Contractor will, as directed by the Project Officer, support, make modifications and update the layout and wording of: the DHQ, an automated self-administered 24-hour dietary recall, or other dietary questionnaires using software that creates machine-readable, web-based, or other types of electronic forms.

Subtask 2.2

The Contractor will, in collaboration with and as directed by the Project Officer, create the codebook and scanning programs necessary to scan dietary questionnaires or create food lists and food probes for an automated self-administered 24-hour dietary recall based on USDA's Automated Multiple Pass Methodology (AMPM) [Raper et al. J of Food Comp and Anal 2004;17:545-555].

Subtask 2.3

The Contractor will, if necessary, create dietary questionnaires, as directed by the Project Officer

Subtask 2.4

The Contractor will analyze data from the AMPM interviews (data provided by NCI) for purposes of determining foods, food probes, and wording to be used in developing or modifying an automated self-administered 24-hour dietary recall.

Subtask 2.5

The Contractor will, as directed by the Project Officer, develop new paper or electronic dietary assessment instruments for use in multiple research settings. Such instruments/software may include, but not be limited to, a food list, food list terms and nutrient database.

Task 3: Other Questionnaire Development Activities

Subtask 3.1

The Contractor will conduct rounds of cognitive interviews or focus groups (of less than 10 respondents) in order to develop or pre-test draft paper-and-pencil or electronic survey questionnaires. The Contractor will be responsible for: a) working with NCI ARP staff, as directed and approved by the Project Officer, to develop a

research plan; b) develop advertisements, recruitment materials, or establish means for recruitment at appropriate service organizations (such as an elder-care centers or health clinics); c) recruit individuals having a wide variety of demographic and health-related characteristics; d) schedule interviews and other related logistics; e) conduct approximately one-hour long focus groups or interviews, as needed, including appropriate incentives; and f) write-up group or interviewing results, with recommendations for changes in questionnaire content and organization. The Contractor will have the capacity to develop and conduct such cognitive interviewing projects with relatively short (e.g., one-month) advance notice.

Subtask 3.2

The Contractor will pre-test existing versions of Computer Assisted Telephone Interviews (CATI) and Computer Assisted Personal Interviews (CAPI) or other electronic instruments used in various projects, and will assist in modifying such instruments, as needed.

Subtask 3.3

The Contractor will create and support all activities (e.g., forms design, codebooks, scanning programs, printing) for electronic or machine-readable instruments.

Task 4: Translation Activities

Subtask 4.1

The Contractor will conduct cognitive interviews to pre-test draft questionnaires, provided or approved by the Project Officer, in a variety of languages as appropriate to the relevant survey and target audience, including at least Spanish and several Asian languages, using translated versions of draft survey questions. For this purpose, the Contractor will select, train, monitor and conduct quality assurance on bilingual cognitive interviewers, with approval of the Project Officer

Subtask 4.2

The Contractor will program and test computerized administration systems, using a programming language that has received prior written approval by the Project Officer, in several languages, as appropriate to the corresponding survey instrument. The Contractor will evaluate each version to ensure that sequencing, program logic and any other program interfaces are identical across versions.

Subtask 4.3

The Contractor will translate survey questionnaires into languages other than English (e.g., Spanish, several Asian languages), evaluate the translated versions via review by bilingual staff, and conduct empirical forms of evaluation that involve analysis of fielded interviews across several languages. In addition, the Contractor will perform behavior coding analysis, when requested by the Project Officer, to determine where questions present overt problems for both interviewers and survey respondents. Further, the Contractor will produce quantitative tabular data detailing frequencies of various coded behaviors at the individual item level and conduct coder debriefings in order to obtain qualitative information related to likely sources of response error.

Task 5: Support for New Components of Previous and Current Projects

Subtask 5.1

The Contractor will conduct activities related to previous and current projects of the Applied Research Program (ARP) that require new or follow-up components not covered under existing study-specific contracts, as defined by the Project Officer. The Contractor will work with other contractors or institutions, as needed, to accomplish these tasks. These activities include, but are not limited to:

- a) re-contact of study subjects to disseminate results or collect follow-up information;

- b) conduct medical records searches or searches of databases, such as the National Death Index or tumor registries;
- c) retrieve previously collected information needed for ongoing data analyses of previous projects;
- d) manage data collected as part of a new component to an old survey or project; and,
- e) analyze previously collected data.

Task 6: Biological Specimen Support for Molecular, Biochemical, and Genetics Projects

Subtask 6.1

The Contractor will manage the logistics of biological specimen analyses collected in previous research, working with other contractors or institutions, as needed, to accomplish these tasks, as directed by the Project Officer.

Biological specimen management activities include, but are not limited to:

- a) arranging for biological specimen shipping, processing and storage using safe standardized procedures approved by the Project Officer and in accordance with all local, state and Federal statutes and regulations;
- b) contacting relevant laboratories, and collaborating institutions to arrange for participation in projects, as approved by the Project Officer;
- c) providing of all necessary supplies and materials for the handling and shipment of biological samples, including, but not limited to: blood, tissue, urine, buccal scrapes;
- d) preparing procedure manuals for the processing and storage of biologic specimens, shipment of biologic specimens, submission of specimens to repositories, and tracing of specimens and laboratory results;
- e) collecting pertinent data concerning the originating institution and laboratory, and tracking the handling and disposition of all biological samples, including, but not limited to all irregularities, delays, losses, deteriorations, unplanned de-frostings, accidents, mishandlings, errors, discrepancies and inefficiencies connected with any specimen collection, delivery or storage activity. Problems will be immediately reported to the Project Officer and included in the relevant Progress Report.

Task 7: Development and Management of Small Pilot Studies and Assistance with Preparing Study Materials

Subtask 7.1

Assist the Project Officer in the design and implementation of pilot projects for the ARP (including less than 10 respondents). The pilot projects include, but are not limited to, testing of surveys, methods and other studies. Obtain necessary information to determine effective study resources. Determine the parties whose cooperation or approvals are necessary for implementation of the relevant study (e.g., Federal, state or local government agencies, local institutions such as hospitals, clinics, physicians, community organizations). Negotiate and manage all administrative matters related to the collection of data and specimens with the various collaborating centers (e.g. subcontract, purchase of materials and supplies). Assist in developing protocols and completing forms as defined by the Project Officer for various clearances and committees for the ARP, such as submissions to the Office of Management and Budget (OMB) or Institutional Review Boards (IRBs). Be available to attend such committee meetings, as defined by the Project Officer.

Subtask 7.2

Prepare, pre-test, evaluate and produce study materials, as defined by the Project Officer. Materials include, but are not limited to, questionnaires; data collection forms for abstracting, coding, follow-up, tracking, physical measurements, and exposure assessments; training and procedure manuals for relevant staff, depending on the ARP project.

Subtask 7.3

Train personnel relevant to pilot study research, including, but not limited to: abstractors, interviewers, telephone screeners, coders.

Subtask 7.4

Abstract, create electronic files of, and/or photocopy records (e.g., clinical or office medical records, hospital charts, vital records, job records, etc.), as directed by the Project Officer. Maintain quality assurance and quality control (QA/QC) over the abstracting or copying process or verifications of electronically obtained information.

Task 8: Quality Assurance/Quality Control, Verifications, and Reporting Requirements

Subtask 8.1

Develop and implement quality assurance/quality control (QA/QC) plans for all aspects of data collection, including, but not limited to: staff training, interviewing, and development of tracking systems.

Subtask 8.2

Develop and implement quality control procedures for all projects, including data collection, data preparation and data entry, data coding, data management, and preparation of data files. Use double-blinded coding verification of key variables as requested by the Project Officer. Maintain clearly documented histories of development and updating of databases. Report verification rates, discrepancy rates, and error rates for data collection, preparation and keying following a schedule agreed upon with the Project Officer. Unusual problems should be brought to the immediate attention of the Project Officer.

Subtask 8.3

Develop and implement QA/QC plans for all aspects of biospecimen shipping, and storage. Problems will be brought to the immediate attention of the Project Officer and corrected.

Subtask 8.4

Develop a QA/QC plan for identifying appropriate laboratories and for monitoring quality control within the laboratories as the analysis of actual study samples proceeds. This includes, but is not limited to, biospecimen checks, such as spiked, blank and duplicate samples, and covers collection, disbursement and results transmission. The QA/QC plan should include strategies for obtaining blind quality surveillance for monitoring laboratory procedures.

Task 9: Computer Programming

Subtask 9.1

Use the NIH/CIT computer facility (which has IBM mainframe computers) or an appropriate work station, as approved by the Project Officer and relevant NIH authorizations, accessed by remote terminals to be provided by the Contractor on their own premises.

Subtask 9.2

Design and maintain computer databases and associated reporting software, as approved by the Project Officer.

Subtask 9.3

Prepare and edit computer programs, edit data, and correct computer files when necessary.

Subtask 9.4

Update existing data files with follow-up data, error corrections, as directed by the Project Officer. Maintain clearly documented histories of development and updating of databases, including documentation of any source code that may need to be developed.

ADDITIONAL TECHNICAL INSTRUCTIONS

Attachment 8

1. **Personnel** (examples of the types of personnel who could work on this project):

A. Project Manager (Masters level or above)

The Project Manager should have at least five years of experience managing personnel and directing studies that involved:

- a) developing questionnaires, especially those for dietary assessment, quality of care, health outcomes, and health services, for both self- and interviewer-administration, using varying modes of administration including paper-and-pencil, electronic or telephone;
- b) selecting population samples;
- c) administering telephone, face-to-face, and electronic interviews;
- d) tracking data collections for individuals over time;
- e) assessing reliability and validity of collected data;
- f) editing and analyzing complex questionnaires, including those with dietary components;
- g) transporting analysis of biological specimens;
- h) managing projects with dietary assessment components;
- i) training and quality control;
- j) translation of questionnaires or interviews;
- k) cognitive interviewing for purposes of developing survey or study questionnaires

B. Programmer/Analyst

The Programmer/Analyst should be experienced in supervising personnel, writing and implementing data management systems, and manipulating and analyzing large data sets. Experience in manipulation and analysis of dietary data preferred.

C. Psychologist (Masters level or above)

The Psychologist should be experienced or trained/experienced in methods of cognitive psychology for purposes of designing, administering, and analyzing surveys or questionnaires. This experience should include methods of designing, conducting and analyzing multiple rounds of cognitive testing of research questionnaires for self-administered (both paper-and-pencil and electronic) and interviewer administered questionnaires.

D. Nutritionist (Masters level or above)

The Nutritionist should have at least five years of experience in:

- a) administration of multiple dietary assessment instruments including multiple types of food frequency questionnaires, food records, and 24-hour recalls (including NDS-R);

- b) analyzing national dietary data (Continuing Survey of Food Intake by Individuals or the National Health and Nutrition Survey) including food lists, recipe files, and dietary supplement files, including knowledge and use of the Automated Multiple Pass Methodology (AMPM) developed by the US Department of Agriculture;
- c) the use of such instruments and their appropriate modification for population surveys or epidemiologic research studies;
- d) the editing of responses to dietary assessment instruments, particularly the Food Frequency Questionnaire and the 24-hour recall;
- e) the use and manipulation of nutrient databases in the analysis of both 24-hour dietary recalls and Food Frequency Questionnaires

II. Corporate Resources

Offerors should describe the availability of resources, which should include a centralized facility in which documents associated with multiple projects can be stored and secured. The facility/office should be located so that stored materials and reports can be reviewed by NCI program or contracting staff. The facility/office should have sufficient resources for all types of materials received and subsequently delivered, as specified in the Statement of Work and Deliverables.

III. Biological Specimens

To assist in the estimation of costs, it is anticipated that the following types of biological specimens may need to be accessed, shipped and tracked by the Contractor: blood, urine, tissue and buccal scrapes.

IV. Travel

One trip per year to Rockville, MD is anticipated to meet with the Project Officer.

V. List of Government Provided Databases/References

The Contractor will be required to access and, under direction of the Project Officer, use or modify databases, including, but not limited to, the following:

1. <http://riskfactor.cancer.gov/tools/instruments/>
2. <http://healthservices.cancer.gov/>
3. <http://www.ars.usda.gov/services/docs.htm?docid=7673>
4. <http://www.ars.usda.gov/services/docs.htm?docid=7710>
5. <http://www.ars.usda.gov/services/docs.htm?docid=7716>
6. <http://www.cdc.gov/nchs/nhanes.htm>
7. <http://www.nal.usda.gov/fnic/foodcomp/data/>

VI. Technical/project Risk

The following provision will be incorporated into the Advance Understandings of the resultant contract:

It is understood that if the work delivered is of poor quality, the Contractor will be required to redo the task at no additional cost to the Government, e.g., translations that are not accurate or complete will be redone and resubmitted in a timely manner at no additional cost to the Government.